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FAIRVIEW CANCER REHAB PROGRAM OUTCOMES AND EFFECTIVENESS:
A PILOT STUDY

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ABSTRACT

BACKGROUND AND PURPOSE: One million people in the United States of America are diagnosed with cancer each year. Many cancer patients are surviving and managing residual effects of cancer, including, but not limited to pain, muscle weakness, depression, anxiety, fatigue and decreased activity tolerance. The purpose of this study is to initiate data compilation to determine the effectiveness and outcomes of the Fairview Cancer Rehabilitation program.

METHODS: Participants included 7 patients with a wide variety of cancer diagnoses who were consecutively recruited from Fairview Cancer Rehabilitation program. This program included physical and/or occupational therapy targeted to each patient's individual impairments. Outcome measures included FACIT-Fatigue, Short-Form Health Survey (SF-12), Six-Minute Walk Test (6MWT), Timed Up and Go (TUG), bilateral grip strength, Numerical Pain Rating Scale (NPRS) and a follow-up survey inquiring about current health status, activity level and pain rating. Outcome measures were administered within the first 2 physical therapy visits and re-administered at time of discharge. The follow-up survey along with the SF-12 were mailed to each participant at 2 months post discharge. Since the number of subjects included in this study was low, changes in scores were examined for trends.

RESULTS: The participants ranged in age from 24 to 66 years with an average age of 51.4 ± 14.3 years. Patients participated in an average of 9.6 physical therapy visits ranging from 4-17 visits. Patients participated in an average of 3.1 occupational therapy visits, ranging from 0-12 visits. Mean FACIT-F, SF-12 physical and mental composite scores, 6MWT, TUG scores, bilateral grip strength and NPRS demonstrated impairments at initial evaluation and demonstrated improvement at post-intervention assessment. SF-12 mental composite scores and NPRS continued to improve from the post-intervention to follow-up measures.

CONCLUSION: Patients with cancer and cancer survivors are living with a variety of side effects. This pilot study supports the effectiveness of Fairview Cancer Rehabilitation program in improving patient's quality of life and functional abilities. Further research is indicated with a larger sample size and increased follow-up time.

The undersigned certify that they have read, and recommended approval of the research project entitled...

FAIRVIEW CANCER REHAB PROGRAM OUTCOMES AND EFFECTIVENESS:
A PILOT STUDY

Submitted by
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Allie Meier
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In partial fulfillment of the requirements for the Doctor of Physical Therapy Program

Primary Advisor *Ruma Chatterjee* Date 4-29-14

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Chapter 1: Introduction

According to the American Cancer Society, over one million people in the United States of America are diagnosed with cancer each year with males having a 44% chance of being diagnosed with some form of cancer in their lifetime and females having a 38% chance. Males diagnosed with cancer have a 23% chance of dying from that cancer, and females have a 19% chance.¹ According to the National Cancer Institute, the cancers diagnosed in the United States of America at the greatest frequency are: bladder, breast, colon and rectal cancer; endometrial cancer; kidney, lung, prostate, pancreatic and thyroid cancer; along with leukemia, Non-Hodgkin lymphoma and melanoma.² As cancer treatment has improved, many patients with cancer are surviving and dealing with the residual effects of the cancer and cancer treatment such as chemotherapy, radiation, and other medications.

The residual side effects can lead to cancer-related impairments including but not limited to: pain, depression, anxiety, and asthenia, a pathological degree of fatigue leading to decreased activity tolerance, impaired coordination, difficulty initiating activity, and memory loss.³ Cancer-related fatigue affects 30% of cancer survivors post treatment, which then significantly impacts their quality of life.⁴ Patients with cancer who have concurrent fatigue, sleep disturbances, depression and pain have difficulty with functional activities which can again negatively impact quality of life.⁵ It has been shown that after patients with cancer receive chemotherapy treatment, they have increased postural instability, which may impair balance.⁶ Additionally, with fatigue, inactivity and prolonged bed rest due to the side effects of tumor factors and medications, skeletal

muscle atrophies at a rapid rate leading to decreased muscle strength.⁴ As a result of these impairments, limitations in functional activities may occur, therefore, leading to the need for cancer rehabilitation.

According to a recent national health interview survey, cancer survivors were significantly more likely to report fair or poor health, psychological disability, limitations with activities of daily living and instrumental activities of daily living, functional limitations, and inability to work due to health conditions. This reflects the need for cancer rehabilitation programs to assist in improving the quality of life of those with a history of cancer by utilizing an individualized program to match the specific impairments and functional limitations of the individual.⁷

Cancer rehabilitation programs consist of a variety of interventions. It is important for persons to participate in physical therapy due to the risk of continued muscle atrophy and deconditioning that may occur with inactivity as well as due to the numerous impairments that can result from treatment. Recent studies have demonstrated that physical activity in cancer survivors can improve aerobic capacity, muscle strength, body composition and quality of life.⁴ Physical therapy should include interventions that specifically address each individual's impairments resulting from the cancer and cancer treatment. This may include a progressive strengthening program to increase lean muscle mass, aerobic exercises for conditioning, along with some balance and coordination exercises. Due to the individualized nature of each physical therapy session to cater to the needs of the patient, there is not a standard protocol to follow with a cancer survivor

patient population. However, outcome measures specific to these impairments can evaluate the effectiveness of therapy in resolving these impairments.

Outcome measures for cancer rehabilitation programs should focus on addressing the impairments and activity limitations of each individual. The residual effects of cancer treatment and inactivity often lead to fatigue, decreased quality of life, decreased activity tolerance, decreased strength, pain and decreased balance. Since these are common impairments addressed by the cancer rehabilitation program, the effectiveness of this program can be measured by utilizing related standardized outcome measures.

Standardized outcome measures for these constructs include the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) for fatigue, the SF-12 to assess quality of life, the six-minute walk test for activity tolerance, grip strength as a predictor of general strength, numerical pain rating scale for pain, and the Timed Up and Go test for balance.

The Fairview HealthCare System instituted a cancer rehabilitation program in 2010, which exists to improve the function and quality of life for people who have had treatment for cancer. The effectiveness of multi-disciplinary cancer rehabilitation programs such as the one instituted by Fairview has not been extensively investigated. Thus, the purpose of this study was to initiate data compilation to determine the effectiveness and outcomes of the Fairview Cancer Rehabilitation program through pre- and post-treatment outcome measures and a two-month follow-up survey of cancer survivors participating in physical therapy, or physical therapy and occupational therapy.

Chapter 2: Review of Related Literature

Physical Activity in the Cancer Patient Population

There have been several studies that have highlighted the positive effects of physical activity on cancer-related impairments. De Backer et al. demonstrated the benefits of cancer survivors participating in a high intensity strength program.⁴ In the study, carried out in the Netherlands, 57 patients who had received chemotherapy for lymphomas, breast, gynecologic, testicular, or colorectal cancer participated in an 18 week high intensity strength training program and interval training. The strength training consisted of six exercises targeting large muscle groups: vertical row, leg press, bench press, pull-over, abdominal crunch and lunges. Strength training began with two sets of ten at 65%-80% of 1-rep maximum (RM) for the first 12 weeks. The progression at 12 weeks consisted of focusing on muscle endurance by increasing the repetitions to 20, and decreasing resistance to 35-40% of 1-RM. The interval training consisted of cycling two times eight minutes at various intervals each 30 seconds before the strength program. Every four weeks the training progression was evaluated, weights were adjusted according to new 1-RM. The results demonstrated significant improvement in muscle strength using 1-RM (effect size 1.32-2.68), an increase in VO2 max by 10% for males and 13% for females, along with significant improvement in health-related quality of life.

Midtgaard et al. demonstrated the need for cancer patients to attend a supervised exercise program in order to obtain the most significant benefits from the physical activity.⁸ The study, carried out in Denmark, examined short-term exercise adherence of cancer patients following a six-week supervised exercise program that was focused on

muscle strengthening, cardiovascular fitness, relaxation, body awareness and massage.

There was a significant decrease in patient adherence in continuing with physical activity following the supervised exercise program at six weeks to eighteen weeks according to semi-structured interviews. Given this data, it suggests the continued need for supervised programs to encourage and support cancer patients and survivors to be physically active. Further research is needed to determine the appropriate length of an exercise program to ensure patient adherence.

Research has continued to show the benefits of exercise with many patient populations including those with cancer or survivors of cancer. Hatchett et al. examined the effects of a 10-week rehabilitation program based on physical activity specifically for cancer survivors.⁹ Patients engaged in individual and group exercise sessions two times per week with exercises focusing on strength, cardiovascular fitness, flexibility and relaxation. The results demonstrated a significant change in strength, fatigue and depression among patients according to the outcome measures of 30-sec chair stand, Brief Fatigue Inventory and Beck Depression Inventory II. These physiological changes and behavioral benefits further demonstrate the need for cancer survivors to participate in physical activity such as a cancer rehabilitation program can provide.

Cancer Rehabilitation Programs

Limited research has been published on the effectiveness of cancer rehabilitation programs. As a result of the individual needs of each patient, there is no standard protocol; however, rehabilitation is aimed to positively combat cancer-related impairments. One study by Clark et al. demonstrated the benefits of a team approach

cancer treatment including physical therapy.¹⁰ This randomized control trial consisted of 131 patients with cancer undergoing radiation. Controls received standard medical care, whereas, the experimental group received standard medical care as well as care from a multi-modal team including a physical therapist, a psychologist/psychiatrist, advanced practice nurse, clinical social worker and certified hospital chaplain. At one-month follow-up, the experimental group had significantly better quality of life compared to the controls. Although there is limited research determining the benefits of cancer rehabilitation, it is becoming common practice for patients to receive the option of attending a cancer rehabilitation program. Silver et al. discussed two systematic reviews, Mewes et al. and Heitland et al., which support the cost-effectiveness of cancer rehabilitation programs.¹¹

Outcome Measures

As the research has demonstrated, individuals that have cancer or who are currently going through treatment suffer from fatigue, pain, and decreased strength, endurance, and quality of life. To measure the change between pre- and post- cancer rehabilitation, six outcome measures were selected. Each outcome measure aimed to measure the symptoms that are common in the oncology population.

Fatigue, pain and quality of life are subjective experiences and therefore self-rated measures were used to assess these dimensions: FACIT-F, numeric pain rating scale and SF-12 respectively. The six-minute walk test was used to assess endurance, the Timed Up and Go test was used to assess balance (a complication of weakness and neuropathy) and mobility, and grip strength were used to assess strength.

The Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)

The FACIT-F is a 13 item questionnaire that assesses one's level of fatigue while doing everyday activities using a Likert self-report scale from 0 (not at all) to 4 (very much so). It assesses the individual's level of fatigue for the past seven days. The questionnaire is scored ranging from 0, indicating the worst condition, to 52, indicating the best condition.¹² A scoring rubric can be found in appendix E, which dictates that the US general population average score is 40 with a standard deviation of approximately 10. The FACIT-F is a subscale of The Functional Assessment of Chronic Illness Therapy-General (FACIT-G), which is a 41 item questionnaire that has five domains including: physical well-being, social/family well-being, emotional well-being, functional well-being and fatigue. The FACIT-F was developed in 1994-1995 to evaluate fatigue in patients with anemia.

This scale is appropriate to use with this population as it has been validated on oncology patients and the fatigue subscale showed strong internal consistency with coefficient alpha range = 0.93-0.95.¹³ The FACIT-F has been validated against the Piper Fatigue Scale ($r = -0.75$), Profile of Mood States-Vigor (POMS-V) ($r = 0.66$), POMS-fatigue ($r = -0.74$), and the Marlow-Crowne, a social desirability scale ($r = 0.04$)¹³. The Minimal Important Difference in a cancer population was found to be 3 points by Cella et al.¹⁴ The FACIT-F was utilized due to the high incidence of fatigue in those with cancer. Individuals who are currently receiving chemotherapy and radiation have a higher incidence of fatigue compared to a healthy population.¹⁵ A survey by Carlson et al. of 2776 patients with a history of cancer showed that 48.2% reported fatigue.¹⁶ Cella et al.

conducted a study on US patients with cancer and found that patients who had anemia had a higher level of fatigue than those who have cancer without anemia. The level of fatigue was much higher in those with cancer as compared to a healthy population.¹⁷

Fatigue is defined as extreme tiredness that is not alleviated by rest and can interfere with everyday activities. Fatigue affects one physically, emotionally and psychologically and therefore is a very important component to assess in patients.

Short Form-12 Health Survey (SF-12)

The short form-12 is a condensed version of the quality of life measure SF-36 Health Survey (Appendix C). The SF-36 is a generic health status survey that has been used in a wide variety of populations. It was developed in the United States and has been adopted in many countries as well as the International Quality of Life Assessment Project. There are eight domains on the SF-36. The SF-12 allows one to get a score for the Physical component summary scale score (PCS) and Mental component summary scale score (MCS). The purpose of this was to reduce the burden on the individual filling out the outcome measure without substantial loss of information.¹⁸

In 1998, a cross-validation study by Gandek et al. was conducted in nine European countries (Denmark, France, Germany, Italy, the Netherlands, Norway, Spain, Sweden, and the United Kingdom) to compare the SF-36 and its shorter version the SF-12. These two were found to have a very high correlation ranging from 0.94-0.96 for the physical and mental summary measures respectively. The mean of the SF-36 and SF-12 were within 0.0 to 1.5 points with a median of 0.5 points.¹⁹ There is also evidence of construct validity for older adults, with a statistically significant correlation between

physical health and number of chronic illnesses ($r = .33, p < .05$) and mental health and chronic illnesses ($r = .27, p < .05$), and a statistically significant difference in physical health ($F = 30.5, p < .05$) and mental health ($F = 18.5, p < .05$) between those who exercise regularly and those who do not.²⁰ This data is not based on individuals with cancer, however the SF-12 has been found to be a practical tool to use to evaluate quality of life. In order to promote a high rate of return of the mailed surveys, it was decided that the SF-12 is less demanding of the participant's time and may encourage a higher response rate.

Six-Minute Walk Test

The six-minute walk test (6MWT) is a submaximal VO_2 test used to assess functional exercise capacity/endurance over time. Walking is an activity of daily living, but most often an individual's ability to walk is impaired due to illness, cancer and other medical diagnoses. The test is designed to evaluate the global and integrated responses of all the systems involved during exercise including pulmonary and cardiovascular systems, system circulation, peripheral circulation, blood, neuromuscular units and muscle metabolism.²¹ The American Thoracic Society Pulmonary Function Standards Committee has standardized the outcome measure, creating specific guidelines, in order to improve the psychometric properties.²² The primary outcome for the 6MWT is distance walked in six minutes; however other data can be collected such as dyspnea scale, rate of perceived exertion, heart rate, oxygen saturation, and blood pressure.²³

The 6MWT has evolved into a versatile test with diagnostic utility in many disorders such as COPD, pulmonary hypertension, interstitial lung disease, congestive

heart failure and in pre-surgical evaluation of patients, among others.²² It also has been used in a variety of studies to show improvement in functional exercise capacity, but not in all patient populations. One study demonstrated a significant improvement in 6MWT as an increase by 70 meters with 95% confidence for COPD patients, and for patients with heart failure, a 43 meter increase in the 6MWT was significant improvement, according to another study.²¹ Stevens et al. stated that in healthy individuals the mean 6MWT distance was 580 meters for men and 500 meters for women whereas others have reported a 630 meter average distance for healthy adults.²⁴ Additionally, Simmonds et al. demonstrated excellent reliability and construct validity of the 6MWT within the cancer patient population.²⁵ This study also established 6MWT norms for this specific population ranging from 413.32 meters to 722.50 meters depending on age. It has been demonstrated that patients who underwent chemotherapy treatment due to Non-Small Cell Lung Cancer had significantly lower 6MWT distances in comparison to healthy individuals.²⁶ Overall, the 6MWT has been used and will continue to be used in a variety of patient populations as further research is conducted to show excellent psychometric properties of the test.

Timed Up and Go

The Timed Up and Go (TUG) test assesses mobility, balance, walking ability, and fall risk in older adults. It is a timed test that consists of the patient standing up from being seated in an armchair, walking 10 feet, and turning around to walk back to the armchair, sitting back into the chair completely. In a study of 15 older adults with no history of falls and 15 older adults with a history of two or more falls in the previous six

months, it was shown that a score of greater than 14.5 seconds on the TUG in community dwelling adults indicates a greater risk of falls.²⁷ A study by Siggeirsdottir et al. examined 31 elderly individuals in a retirement home and found that the TUG has excellent inter-rater reliability with a mean difference between raters of 0.04 seconds in this population.²⁸ Steffen et al. demonstrated that the TUG has excellent test-retest reliability with an ICC of 0.97 in community-dwelling elderly people and established normative data for community-dwelling elderly people.²⁹ The mean score was between 8 and 11 seconds depending on age and gender. Podsiadlo et al. found that the TUG has strong criterion validity due to an excellent correlation with the Berg Balance Scale ($r = -0.81$) and with gait speed ($r = -0.61$) in 60 patients with a mean age of 79.5 years who were referred to a Geriatric Day Hospital.³⁰ A prospective study by Lin et al. of 1200 community-dwelling older people in Taiwan found that the TUG has strong construct validity due to an adequate correlation with the Tinetti Balance ($r = -0.55$) and with walking speed ($r = 0.66$).³¹ This study also found that the TUG demonstrates poor responsiveness with a small effect size of 0.12 for falls and 0.05 for ADL improvements. A minimal detectable change (MDC) has not been established for the TUG in either the community-dwelling elderly population or the cancer population. In a study of patients with chronic stroke, an MDC of 2.9 seconds was calculated.³²

Although there is no research on the use of the TUG specifically in the cancer population, patients attending outpatient physical therapy after cancer treatment often have impairments in functional mobility and balance. Therefore it is appropriate to use this quick test that involves components of functional mobility, balance and the

assessment of falls risk. It is crucial that falls risk be assessed in all physical therapy patients in order to prevent further impairments due to either the fear of falling or the trauma associated with a fall.³³

Grip Strength

Grip strength measures the force of the finger and hand flexors during a maximal contraction with a dynamometer to quantify the measurement. The Jamar dynamometer is considered the gold standard for grip strength, however research has shown that other dynamometers are valid and reliable.³⁴ This measurement can be used as an indicator of overall strength.^{35, 36} The standard position for testing grip strength, according to the American Society of Hand Therapists, is with shoulders adducted and neutrally rotated, 90 degrees of elbow flexion, 0 to 30 degrees of wrist extension, 0 to 15 degrees of ulnar deviation, and feet flat on floor.³⁴

There is an abundance of research on grip strength in various cancer populations. Mortality and grip strength has been studied extensively; however research in the cancer population, including correlations between grip strength and cancer specific mortality, is mixed.^{37, 38, 39} This may be due to an inherent difference between cancer and general populations, the length of the study, or the fluctuation of grip strength after a cancer diagnosis. Grip strength has also been correlated with quality of life. Studies of general cancer population and breast cancer specific populations found correlations with physical well-being and quality of life (measured by the European Organization for Research and treatment of Cancer Quality of Life Questionnaire and the RAND-36).^{40, 41, 42}

Using dynamometry to determine grip strength has been found to be both a valid and reliable measure of grip strength. Grip strength has clinical norms for the general population and is highly correlated with age. Clinical norms depend on age and range from 29.8 to 54.9 kg in men, and 5.0 to 31.9 kg in women.⁴³ These norms were established for healthy subjects and are not to be applied to a population of cancer patients. The gold standard is the Jamar hydraulic dynamometer. A prospective study by Bohannon et al. of 28 patients found strong test-retest reliability through a high ICC for both left hand (0.965-0.983) and right hand (0.890-0.975).⁴⁴ Other dynamometers have shown high reliability and grip strength when compared to the Jamar dynamometer and shown internal validity.³⁴

A study with twelve cancer patients with an average age of 60.1 years found the minimal detectable change (MDC) of grip strength to be 3.4 kg with 90% confidence, or 4.04 kg with 95% confidence.⁴⁵ The testers measured grip strength with the Jamar dynamometer using the American Society of Hand Therapist's guidelines.

Numeric Pain Rating Scale

Pain is an important measurement for cancer patients. Approximately 30-50% of all cancer patients experience pain; most of these patients experience life altering pain.⁴⁶ Pain in a cancer population generally is nociceptive somatic, nociceptive visceral, or neuropathic and may be due to the cancer pathology (65-75% of patients) or the cancer treatment (15-25% of patients), with some patients reporting pain unrelated to cancer.⁴⁷ Pain is shown to have significant correlations with overall quality of life and depression in both general populations and cancer specific populations.^{48,49,50,51,52} In cancer

populations, pain is significantly associated with interference with sleep. Intensity and distress associated with pain also significantly correlates with distress from sleep disturbance.⁵⁰

The numeric pain rating scale (NPRS) is a method to verbally or graphically assess a patient's subjective intensity of pain that they are experiencing on an 11-point scale from 0, indicating no pain, to 10, indicating the worst pain imaginable. In a healthy population of 86 adults, intra-rater reliability was shown to be 100% and there was excellent internal consistency of 0.88.⁵³ A double blind peer reviewed study by Paice et al. of 55 patients showed that the verbally administered 11-point NPRS is valid due to its strong and statistically significant correlation with the Visual Analog Scale (VAS).⁵⁴ Two studies showed that the failure rates for the NPRS were lower than for the VAS, indicating that the NPRS is a useful alternative to the VAS.^{54,55} A prospective cohort study by Bijur et al. of a convenience sample of 180 hospital patients presenting with acute pain to the emergency department found that there is a significant correlation of 0.94 between the VAS and NPRS as shown by a slope of regression line of 1.01 indicating a strong level of agreement.⁵⁶ A study by Deloach et al. of 60 patients age 18-86 undergoing surgical procedures disagreed when they found the slope of regression lines at 0.86 and 0.95 for the VAS and NPRS, showing that the scales do not agree.⁵⁷ Due to these contradicting results, it is safe to say that the VAS and NPRS provide similar information, but there is no direct conversion between the scales.

A prospective cohort study of 825 patients with chronic musculoskeletal pain showed that the Minimal Detectable Change (MDC) on the NPRS is a raw change of

three points, whereas the Minimally Clinically Important Difference (MCID), or the change that the patient sees as important, is only one point.⁵⁸ Similarly, a convenience sample of 136 consecutive patients with shoulder pain attending outpatient physical therapy clinics found that the NPRS has a MCID of 2.17.⁵⁹ Serlin et al. found that patients with cancer classify mild pain as a score of 1-4, moderate pain as a 5 or 6, and severe pain as 7 or above on the NPRS.⁶⁰ Patients with cancer were tested in four countries to develop this data and it was found that the severity of pain and its interference with daily functioning is a non-linear scale. Therefore, severe pain drastically limits a person's ability to function in their daily life, whereas mild pain is distracting but usually does not interfere with daily functioning.

The goal of this current study is to determine the effectiveness by assessing each patient's change in the FACIT-F, SF-12, six-minute walk test, grip strength, numerical pain rating scale, and the Timed Up and Go test. The results can help determine if cancer rehabilitation programs such as the one provided by Fairview are beneficial to oncology patients.

Chapter III: Methods

Subjects

The participants for this study were consecutively recruited from the Fairview Cancer Rehabilitation program at the Riverside campus in Minneapolis, Minnesota. The inclusion criterion consists of participants who completed an initial evaluation along with at least four weeks of physical therapy, or combined physical therapy and occupational therapy visits, to address their cancer-related impairments. Participants were excluded if they were under the age of 18 years old and/or were unable to read and write English.

Interventions

Fairview Cancer Rehabilitation program emphasized an individualized physical therapy and occupational therapy program based on each patient's impairments and goals. This program was focused on reducing the side effects of cancer treatment and/or surgery while improving quality of life through physical activity. The physical therapists and occupational therapists working at Fairview Cancer Rehabilitation have additional training and expertise with this patient population (Appendix A and B).

When a participant was referred to outpatient cancer rehabilitation, an evaluation was completed by a physical therapist, and an occupational therapist if it was deemed necessary. Physical therapy (PT) was primarily responsible for strength, aerobic capacity, and range of motion. Each individual was examined and treatment was designed to address the impairments that were found during the initial examination. Interventions may have included strengthening, walking, aerobic conditioning, stretching, and pain management. The goals of physical therapy at the Fairview Cancer Rehabilitation

program included: increase patient strength and endurance; improve range of motion, balance, and flexibility; decrease pain; and reduce nerve discomfort. The goals of OT included: improved attention, organization and problem solving; learning ways to conserve your energy; improve independence in daily activities; and recommendations for adaptive equipment.

There were six educational classes that participants could begin attending at any point in time. The topics included the basics of fatigue, communication & fatigue, body mechanics & making the most of your environment, analyzing & modifying activities, living a balanced lifestyle, secondary fatigue & cognitive fatigue, and safe activity/exercise at home & in the community.

Collection of participant information and medical record data abstraction occurred after the participant was discharged from treatment. Two researchers extracted the data with written consent from each participant. Every measure was taken to ensure that the participant's identity remained confidential. The data obtained from the medical record included age, presence of anemia, pre- and post-rehabilitation outcome measure results, time since chemotherapy and/or radiation treatment, total number of physical therapy and/or occupational therapy visits, medical diagnosis, and physical therapy diagnosis. Additionally, a follow-up survey was sent two months after discharge from the program. For the purposes of completing the follow-up survey, the researchers had access to each participant's mailing address with written consent.

Outcome Measures

The Functional Assessment of Chronic Illness Therapy (FACIT-F)

The FACIT-F is a 13-item questionnaire that required a numerical rating of 0-4 from the participant to score. The physical therapist, occupational therapist, or researcher used the FACIT-F scoring rubric to establish a score (Appendix E). It was administered by a physical therapist or an occupational therapist within the first two visits, at discharge from the program and two months following the patient's discharge. This questionnaire along with the SF-12 and a follow-up survey with four questions were mailed to each participant and the completed measures were scored and analyzed by the researchers (Appendix D).

Short Form-12 Health Survey (SF-12)

The SF-12 is a paper questionnaire that was filled out by the participant. The SF-12 is a condensed version of the SF-36. It contains questions pertaining to one's quality of life. It has both physical and mental components. A copy of the SF-12 can be found in appendix C. This questionnaire was administered three times. The patient filled out the SF-12 within the first two visits, at discharge and two months following discharge. The researchers evaluated the questionnaires.

Six Minute Walk Test

The Six-Minute Walk Test (6MWT) required a 100 foot (30 meters), flat, indoor hallway along with a stopwatch, two cones for marking the turnaround points, and a chair that could be easily moved along the walking course.²³ However, due to space constraints the cones were set up to be 50-60 feet apart. The participant was to be in comfortable clothing and footwear and be at rest sitting in a chair ten minutes prior to the test. The

following instructions were to be given to the patient according to the American Thoracic Society²³:

“The object of this test is to walk as far as you can for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time, so you will be exerting yourself. You probably will get out of breath or become exhausted. You are permitted to slow down, to stop, to rest as necessary. You will be walking back and forth around the cones placed at each end of the hallway. You should pivot briskly around the cones without hesitation. Now I am going to show you (demonstrate). Are you ready to do that? I am going to use a lap counter to keep track of the number of laps you completed. Remember that the object is to walk as far as possible for 6 minutes, but don't run or jog. Start now, whenever you are ready.”

The tester was not to walk with the participant, but could provide an encouraging statement, “you are doing well”, and state remaining time after every minute passed. When six minutes had passed, the therapist was to tell the participant to stop, and proceed to mark the place when the participant stopped walking. The therapist measured the distance of the last partial lap and added it to the distance calculated by the number of laps walked. Additionally, measures such as heart rate, dyspnea, and oxygen saturation could be taken pre and post 6MWT.

Timed Up and Go

The Timed Up and Go (TUG) consisted of the participant wearing their regular footwear and walking at a comfortable walking speed to a line that was 10 feet away,

turning around at the line, walking back to the chair, and then sitting down again with their back completely against the chair. The therapist informed the participant that they would be timed during this test in seconds, with the test ending when their buttock touched the seat. Setting up for the test required the tester to measure and mark a 10-foot walkway and to place a standard height chair with armrests at the beginning of the walkway. The participant should be instructed to sit in the chair with their back against the chair and their arms resting on the chair's arms. If the participant uses an assistive device while walking normally, this should be nearby, but their upper extremities should not be touching it. The therapist demonstrated the test to the participant. When the participant was ready, the therapist says, "Go". The stopwatch started when the tester said go, and ended when the participant's buttocks touched the seat.⁶¹

Grip Strength

Grip strength measurement required a dynamometer and a chair. According to standardized arm positioning by the American Society of Hand Therapists, the patient was instructed to sit with feet flat on the floor, shoulders adducted and neutrally rotated, 90 degrees of elbow flexion, 0 to 30 degrees of wrist extension, and 0 to 15 degrees of ulnar deviation.^{34,43} The participant was then instructed to maximally contract their grip for three seconds and then rest for 15 seconds. The best of three trials was used.³⁴

Numerical Pain Rating Scale

The numerical pain rating scale measured the participant's subjective intensity of pain through either verbal or graphic assessment.⁶² The participant was instructed to indicate the intensity of current, best, and worst pain levels over the past 24 hours on a

scale of 0 to 10, with 0 being no pain, and 10 being the worst pain imaginable.⁶¹

Follow-up Survey

A follow-up questionnaire along with the SF-12 and FACIT-F were mailed to each participant two months after discharge from the program. The questionnaire addressed additional aspects of the participant's life including change in health status, participation in a wellness program, current exercise levels, and pain over that last 24 hours. See Appendix C, D, F and G for information that was sent to each participant.

Data Analysis

The data that was not returned to the researchers through the follow-up survey was extracted from the medical record. This included age, presence of anemia, pre- and post-rehabilitation outcome measures, time since chemotherapy and/or radiation treatment, total number of physical therapy and/or occupational therapy visits, and medical diagnosis (Appendix H). For data collection, two researchers accessed and collected data from the medical record, facilitated by the physical therapy Clinical Quality Liaison at Fairview. Written consent was obtained from each patient in order to complete this data mining. Every measure was taken to ensure confidentiality including keeping digital information encrypted and written information in a locked file cabinet. This data was extrapolated and statistically analyzed to test for significant difference in scores ($p < 0.05$).

The planned sample size was 20 participants. This would be more than adequate to detect changes in the group per sample size calculation of the primary outcome measure SF-12 physical component. It was found that a sample size of at least 12

participants was required to determine a statistically significant difference. A one-way repeated measure ANOVA was planned to be used for outcome measures taken three times. For the measures that have only a pre- and post-test, including the 6MWT, the Timed Up and Go test and grip strength, it was planned to use a paired t-test as this would be equivalent to a one-way repeated measure ANOVA. Time was the independent variable for both of the analysis tests. This would reduce error variance, as the subjects would serve as their own controls.

Chapter IV: Results

A total of seven participants who were receiving therapy from March 2013 through October 2013 were consecutively recruited for this pilot study through the Fairview Cancer Rehabilitation Center. The average age of the participants was 51.4 (\pm 14.3) years old with a minimum age of 24 and maximum age of 66. There were a wide variety of medical diagnoses among the participants, including Acute Myelogenous Leukemia, Stage IIB Serous Carcinoma of Ovarian or Fallopian Tube, Diffuse Histiocytic Lymphoma, Breast Cancer with and without Lumpectomy, Squamous Cell Lung Cancer, and Stage IIIC Grade II Endometroid Adenocarcinoma. The mean amount of time since the participants had received treatment for cancer was 2.29 (\pm 4.3) months, with a minimum of 0 months if they were currently receiving treatment and a maximum time of 11 months. The participants attended physical therapy for a mean of 9.6 (\pm 4.3) visits, with a minimum of 4 and a maximum of 17 visits. The participants went to occupational therapy for a mean of 3.1 (\pm 4.3) visits, with a minimum of 0 and a maximum of 12 visits. There were 3 participants who, based on hemoglobin levels, were anemic at the time of the physical therapy evaluation, and 3 participants that were not anemic. Information was not available about the anemia status of one participant.

The intent of this study was to do statistical analysis of the data, however as a result of the low number of participants ($n=7$), the data was examined for trends, as the results could not be extrapolated to the greater population. Instead, the mean scores and the standard deviations were examined to determine if outcomes were trending towards

improvement. All scores improved from the time of pre-treatment to post-treatment, and continued to improve from post-treatment to follow-up.

FACIT-F

The pre-treatment FACIT-Fatigue mean score was 28.14 (± 11.41). The post-treatment FACIT-Fatigue mean score was 39.00 (± 9.93), indicating a positive trend toward improvement. The average U.S. FACIT-Fatigue score is 40; however no MDC has been established for this outcome (Appendix E).

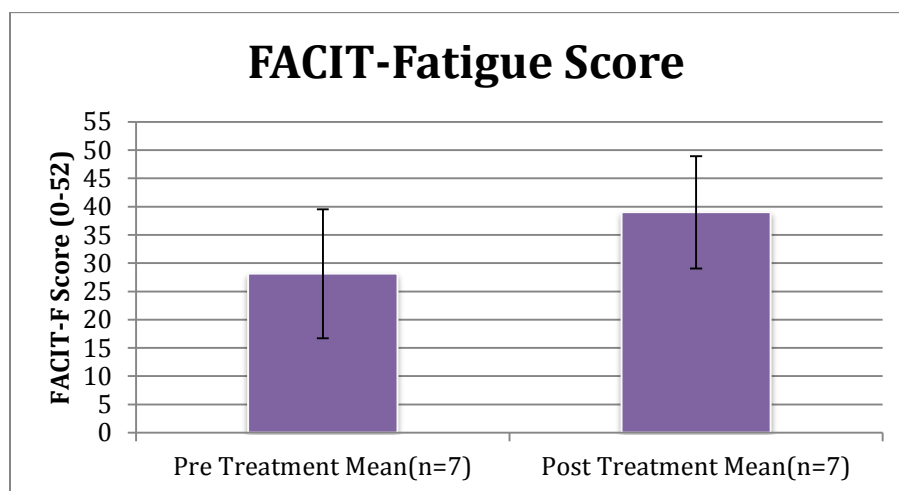


Figure 1. Bar graph showing mean FACIT-Fatigue scores before and after treatment. Error bars indicate the standard deviation of each.

SF-12

The pre-treatment SF-12 Physical Composite mean score was 40.00 (± 10.88), the post-treatment mean score was 47.60 (± 9.22) and the 2 month follow up mean score was 49.42 (± 7.55), indicating a positive trend of improvement. Four of five participants improved their SF-12 physical composite scores from pre-treatment to post-treatment, and four out of four improved from pre-treatment to follow-up. No participants improved from post treatment to follow up.

The pre-treatment SF-12 Mental Composite mean score was 45.26 (± 6.98), the post-treatment mean score was 51.48 (± 5.56) and the 2 month follow up mean score was 56.86 (± 3.15), indicating a positive trend towards improvement on this outcome from time of pre-treatment to the 2 month follow up. There has not been a MDC established for this outcome, however the national average on the SF-12 is a score of 50. Three out of 5 participants improved their SF-12 mental composite score from pre-treatment to post-treatment, three out of four improved from pre-treatment to 2 month follow-up and two out of three improved from post treatment to follow-up; however at the time of the follow-up survey all scores were at or above the average score of 50.

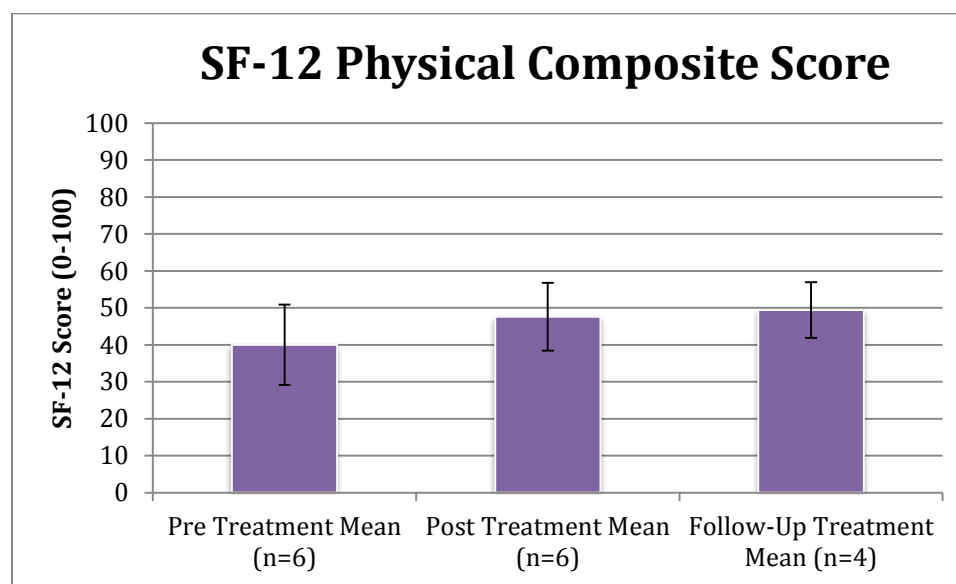


Figure 2. Bar graph showing mean SF-12 Physical Composite scores before treatment, after treatment, and at follow-up. Error bars indicate the standard deviation of each.

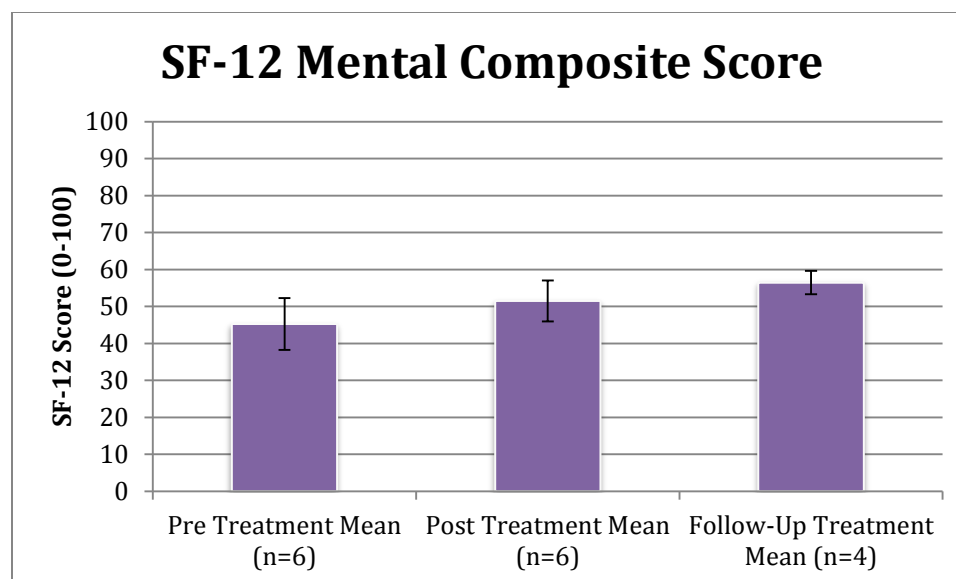


Figure 3. Bar graph showing mean SF-12 Mental Composite scores before treatment, after treatment, and at follow-up. Error bars indicate the standard deviation of each.

Six-Minute Walk Test

Pre-treatment mean 6MWT among the participants was 409.74 (± 161.6) meters; the post-treatment mean for the 6MWT was 505.49 (± 112.990), indicating a positive trend towards improvement on this outcome. The MDC for the purposes of this study is 70 meters, indicating a meaningful change between the pre-treatment and post-treatment. Five out of seven patients improved from pre- to post-treatment by greater than 70 meters to show significant change.

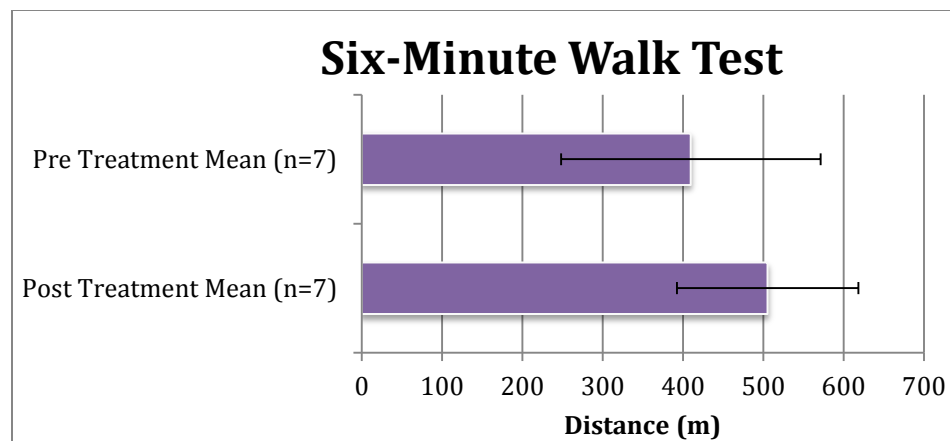


Figure 4. Bar graph showing mean Six-Minute Walk Test scores before and after treatment. Error bars indicate the standard deviation of each.

Grip Strength

The participants demonstrated improvements in grip strength bilaterally. The pre-treatment right-handed grip strength mean was 57.00 (± 20.40) pounds, and the post-treatment right-handed grip strength mean was 67.29 (± 27.12) pounds. The mean pre-treatment left-handed grip strength was 55.43 (± 21.45) pounds, and the mean post-treatment left-handed grip strength was 65.14 (± 26.69) pounds. The MDC for this outcome is 8.9 pounds, indicating a positive trend towards improvement on this outcome. Six of seven participants improved their right grip strength, however, four of six improved significantly according to the MDC. Six of seven patients improved their left grip strength significantly.

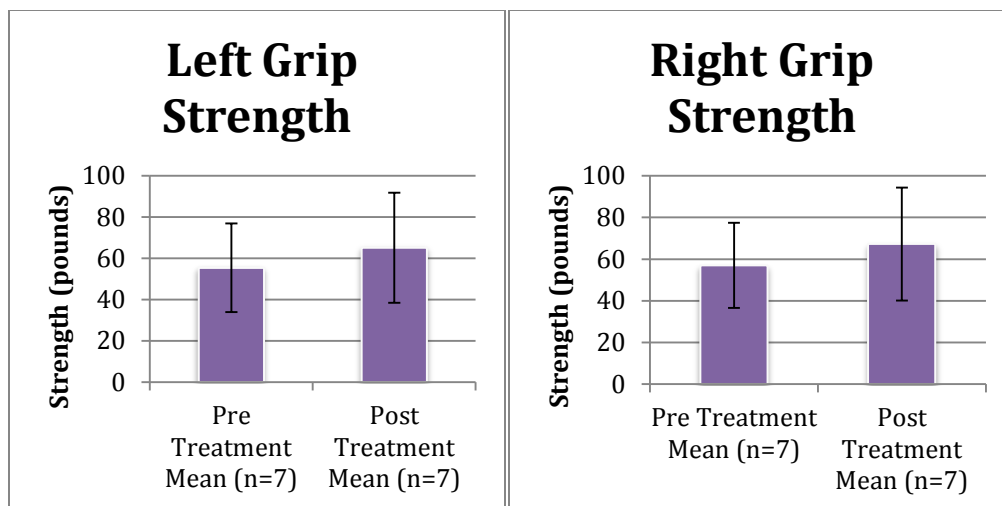


Figure 5. Bar graph showing mean grip strength scores for left and right hands before and after treatment. Error bars indicate the standard deviation of each.

Timed Up and Go

The pre-treatment TUG mean time was 8.975 (± 2.67) seconds, and the post-treatment TUG mean time was 7.635 (± 1.52) seconds, which demonstrates a trend towards improvement with 5/6 participants decreasing their timed score. However, the difference between the pre-treatment means and the post-treatment means were not large enough to satisfy the MDC of 2.9 seconds, with the exception of one participant.

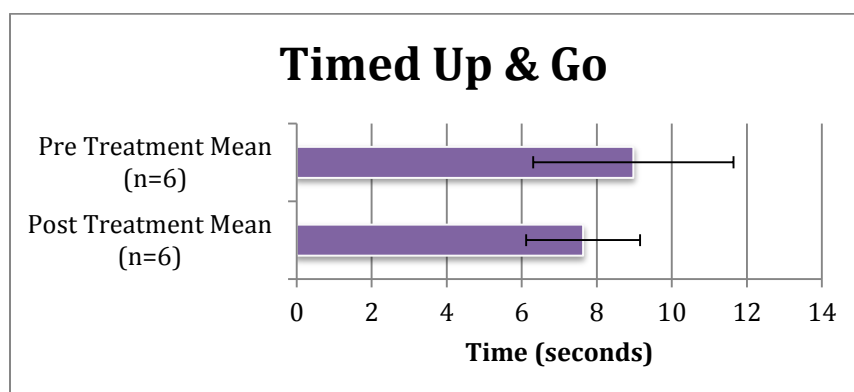


Figure 6. Bar graph showing mean Timed Up & Go scores before and after treatment. Error bars indicate the standard deviation of each.

Numeric Pain Rating Scale

The pre-treatment mean NPRS was 5.43 (± 2.69), the post-treatment mean NPRS was 2.71 (± 2.87) and the 2-month follow-up mean NPRS was 1.4 (± 1.95), demonstrating a trend towards improved pain ratings. Six out of seven participants had improved pain from pre to post treatment, with three of those six improving by the MDC of three points. Five out of five improved from pre-treatment to follow-up, with two of five improving by the MDC. Two out of two improved from post treatment to follow-up, one of those improving by the MDC. However, it is important to consider that one point has been found to be a meaningful change in pain to a patient.

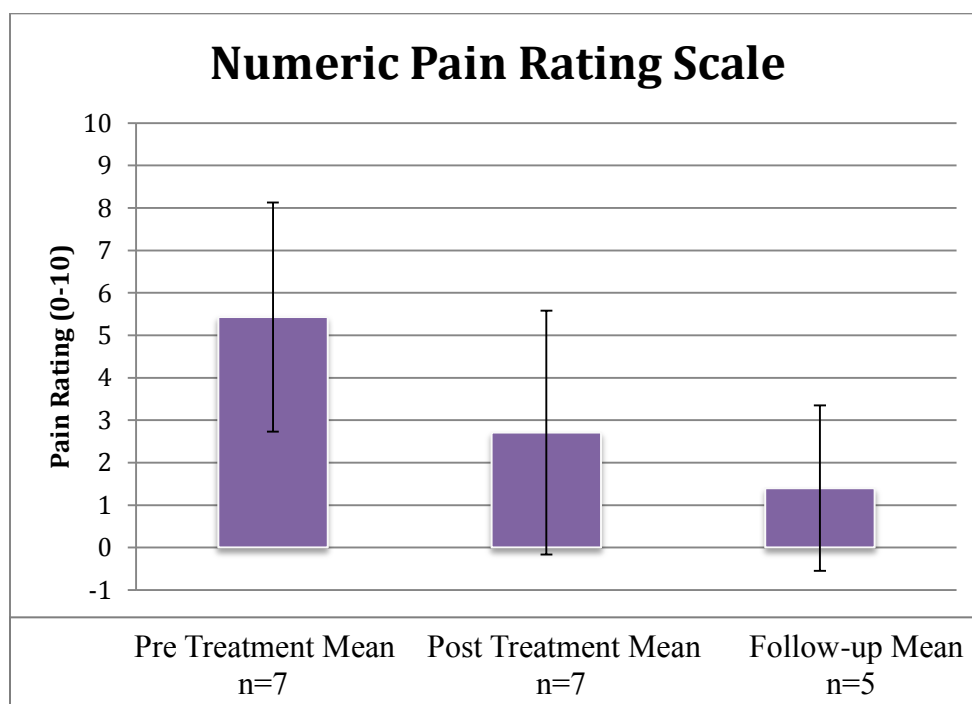


Figure 7. Bar graph showing mean Numeric Pain Rating Scale scores before treatment, after treatment, and at follow-up. Error bars indicate the standard deviation of each.

Follow-up Questionnaire

Participants were asked how many minutes they spent exercising at the beginning of treatment and asked again on the 2-month follow-up survey. Pre-treatment, participants shared that 57.1% exercised 0 minutes per week, 14.3% exercised 31 to 60 minutes a week, 14.3% exercised 91 to 120 minutes per week and 14.3% exercised more than 151 minutes per week. In the 2-month follow-up survey, 28.6% exercised 30 minutes or less a week, 14.2% exercised 121 to 150 minutes per week, 28.6% exercised 151 or more per week, and 28.6% of participants did not disclose this information in the follow-up survey. This indicates that more participants exercised after treatment and for longer durations, however the data could not be analyzed for statistical significance.

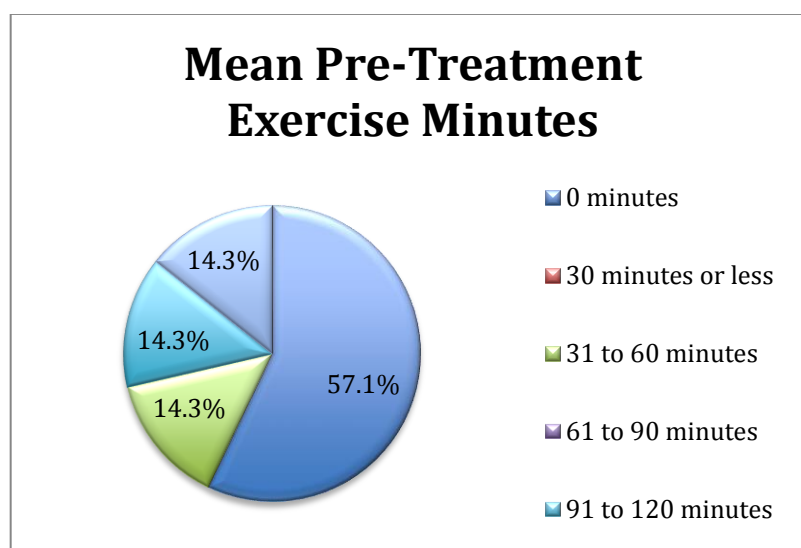


Figure 8. Pie chart showing mean pre-treatment exercise minutes.

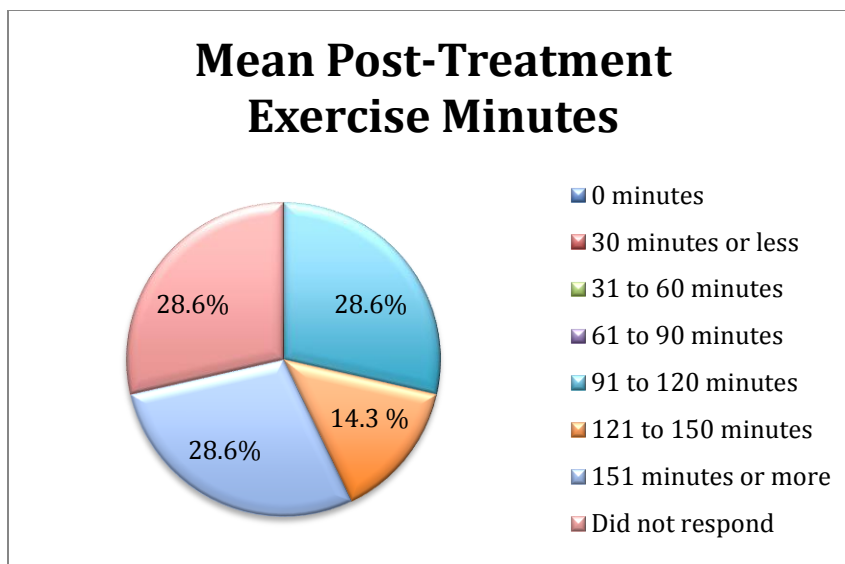


Figure 9. Pie chart showing mean post-treatment exercise minutes.

Chapter V: Discussion

Cancer related impairments impact many facets of an individual's life. Currently, there is limited knowledge on the effectiveness of individualized cancer rehabilitation programs. The results of this study demonstrate trends of improvement in all outcome measures addressing a variety of aspects of life including fatigue, mental health, physical activities, pain and endurance. Although the data could not be analyzed for statistical significance secondary to the low number of participants, the data suggests that Fairview's Cancer Rehabilitation program had a positive impact on the patient's quality of life as well as physical and mental functioning.

A recent literature review discussed the importance of cancer rehabilitation in the continuum of care, from those who are recently diagnosed to those who are cancer survivors.¹¹ More and more patients are surviving cancer; however, the treatment for cancer still is toxic to the human body. Due to the side effects of the cancer treatment drugs, along with the cancer and possible surgery, cancer survivors are living with many physical and psychological issues. Health-related quality of life in cancer survivors is much worse than others; approximately 1 of 4 cancer survivors reported poor physical health and 1 of 10 reported poor mental health.¹¹ Both physical and mental health play a role in quality of life. Examples of functional assessment tools that focus on screening impairments for physical and psychological issues include the SF-36, TUG, 6MWT, visual analog scale and FACIT-F.¹¹ This study used the SF-12 to examine the global health of each participant, the numerical pain rating scale, the FACIT-F to assess fatigue,

along with a variety of physical outcome measures including the TUG, 6MWT, grip strength.

A multi-disciplinary approach and “fast-track rehabilitation” to treating a variety of cancers has been shown to result in better outcomes.⁶³ Fast-track rehabilitation refers to rehabilitation intervention during active cancer treatment. There are many factors that may contribute to the quality of life of a patient with cancer including comorbidities and lifestyle factors; however, rehabilitation may help prevent the decline of quality of life for these patients, including preventing excessive fatigue.⁶⁴ Additionally, cancer survivors that received exercise intervention after their cancer treatment were shown to have improved health-related quality of life and had beneficial effects in domains such as body image, fatigue, and anxiety as demonstrated in a recent Cochrane Database Review.⁶⁵ The Fairview Cancer Rehabilitation program assessed each patient’s impairments and needs to create an individual program to improve their fatigue, strength and endurance along with providing key educational interventions.

A prospective intervention study supports educational sessions for patients with cancer in order to improve quality of life and reduce cancer-related fatigue distress.⁶⁶ Their education program included risk factors and management strategies for cancer-related fatigue, exercise instruction, energy conservation and Tai Chi. The Fairview Cancer Rehabilitation program offered weekly educational classes that participants could choose to attend. The topics included: basics of fatigue, communication & fatigue, body mechanics & making the most of your environment, analyzing & modifying activities,

living a balanced lifestyle, secondary fatigue & cognitive fatigue, and safe activity/exercise at home & in the community.

Limitations

There were limitations to this study as a result of the nature of variability in working with a patient population. The low number of participants in this study who completed all outcome measures and a lack of a control group limit the power of this study in establishing effectiveness of the intervention.

Establishing rapport between a therapist and a patient is crucial to providing a plan of care that fits the individual. As a result of this, the time and manner in which questions and outcomes measures were administered were not identical. There was a lack of consistency in the way questions were asked. The number of minutes spent exercising was asked verbally without categories initially while the follow-up questionnaire required an ordinal response, which made the data difficult to interpret. The follow-up pain rating was specific in asking about pain in the past 24 hours whereas during therapy the participants may have reported their current pain rating. There should have been consistency in how the NPRS was administered.

This study included a follow-up survey, which not all participants sent back. Two participants did not send back the follow-up survey, SF-12 and FACIT-F. Three participants did not send back the FACIT-F, but did send the follow-up survey and SF-12. Another limitation is that not all participants answered all of the questions on the SF-12 and the FACIT-F, making it difficult to compare data.

This research was also limited by a follow-up time of only 2 months. Chemotherapy and radiation therapy may include late side effects which manifest anywhere from weeks to years after radiation treatment. These include adverse effects that can impact physical therapy outcomes such as anemia, fibrosis, cirrhosis, atrophy and neural damage.^{67, 68} Overall, there are improvements that could be made to improve the quality of data that was collected.

Future Research

As this was a pilot study, a major path for further research is to increase the number of participants involved in the study. More participants would allow for increased power and an increased ability to determine statistically significant results. Increasing the length of time between discharge from physical therapy and the follow-up survey would increase the amount of time since oncological treatment and allow for a better understanding of the effects of the cancer rehabilitation on these outcomes.

Further research may include broadening the data collection to include body mass index (BMI) and sleeping disruptions. A prospective study of breast cancer patients found that those on the extreme ends of the BMI scale (highest and lowest BMI) are significantly correlated with increased risk of mortality.⁶⁹ Exercise has been shown to improve BMI to a healthy range. Winningham and colleagues found that 20-30 minutes of exercise, three times a week for 10-12 weeks has been shown to decrease fat tissue and increase lean muscle mass in patients with stage II breast cancer when compared to non-exercising controls.⁷⁰ Forty to sixty percent of patients with cancer report sleep difficulties from the start of treatment to up to one year. Mock and colleagues found

significant improvements of sleep in patients with stage I and stage II breast cancer who participated in a cancer rehabilitation program, when compared to controls who did not.⁶⁹

This study did not cover the effect of pre-rehabilitation on outcomes for therapy post or during treatment. Pre-rehabilitation consists of interventions before cancer treatment or surgery to determine if the patient has any current impairments and therefore then address those impairments with therapy.¹¹ Pre-rehabilitation has been shown to be effective in improving pulmonary function in patients with lung cancer when compared to controls 4-6 weeks after cancer surgical treatment. Further research on whether subjects who participated in a pre-rehabilitation program would be helpful in better understanding the effects of post and peri-treatment rehabilitation.

Chapter VI: Conclusion

The purpose of this study was to provide Fairview and their patients who have cancer with data regarding the effectiveness of the cancer rehabilitation program. Patients with cancer and cancer survivors are living with a variety of side effects that impact their quality of life and functional abilities. The results of this pilot study supports the effectiveness of Fairview Cancer Rehabilitation program in improving participant's fatigue level, quality of life, activity tolerance, grip strength, pain and balance with physical and/or occupational therapy in an outpatient setting. The results suggest that these patients maintain improvements in their quality of life and pain levels with involvement in exercise in a community setting even after they have completed therapy. Expanding data collection of this study on a larger scale would be feasible, but would be limited by a lack of patient adherence in completing the follow-up survey. Further research is indicated with a larger sample size and increased follow-up time.

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Appendix A

CANCER REHAB PHYSICAL THERAPY EVALUATION

EVALUATION RECOMMENDATIONS:

Subjective:

- Type of cancer, including stage and grade
- Previous and/or pending surgeries
- Significant past medical history
- Lymph node dissection, including number of nodes removed and the number positive for cancer
- Chemotherapy treatment and side effects
- Radiation therapy and side effects including presence/absence of fibrosis, decreased joint ROM, tight tissues, and skin redness
- Pain, including rating scale type
- Presence/absence of numbness/tingling
- Lab Values including WBC, Platelets, Hemoglobin, and Absolute Neutrophil Count (ANC)
- FACIT-F: To assess cancer-related fatigue (see page 4 for additional details including administration)

Objective:

- Postural changes
- ROM/Flexibility
- Check joints impacted by surgery or radiation which may include:
 - Trunk
 - Shoulder: elevation, IR/ER
 - Hip flexion, extension, IR/ER
 - Knee flexion/extension
 - Ankle PF/DF
- Muscular strength and Muscular Endurance
- Check all areas that are near surgical sites or have been radiated:
 - Manual Muscle Testing
 - Measure isometrics-use dynamometer for grip strength and pinch gauge for 3 jaw chuck and lateral pinch
 - One Repetition Maximum (RM) Test or estimate of 1 RM by having patient do 10 repetitions at heaviest weight they are comfortable with and convert to 1RM by dividing the weight by .75
 Example: If pt completes 10 bicep curls with 10 pounds: $10\# / .75 = 13.3 \#$
 For many pts this may initially be only ROM without weights
- Sensory Testing:
 - Semmes-Weinstein Monofilaments, Modified Total Neuropathy Score
- Vestibular/Balance:

- Balance testing: TUG, Tinetti, Berg, Dynamic Gait Index.
- Some patients have vestibular dysfunction-ototoxicity, onset caused by chemotherapy, viral (immunosuppression) or idiopathic with sudden onset of dizziness and vertigo.
- Acute symptoms resolve within 24-72 hours. Residual deficits which can be treated by PT. If vestibular is affected bilaterally may have severe balance deficits as well as hallmark c/o oscillopsia.
- Refer to vestibular trained therapist as appropriate.
- Tissue texture including edema, pitting, fibrotic areas
- Incisions including adhered or mobile areas
- Cardiorespiratory Fitness:
 - 6 minute walk test (submaximal exercise test): record distance
 - Heart rate: record pre/post, oxygen saturation: pre/post, blood pressure: pre/post
 - TUG test (if unable to complete 6 minute walk test): record time
 - BMI
 - Muscle endurance: Bicep curl test: (female 5#/male 8#), record number of repetitions

Specifics by cancer type:

For breast cancer:

- UE strength/ROM grip strength
- Pain/ tightness in pectoralis major/minor, subscapularis
- Axillary cording
- Glenohumeral and scapulothoracic joint mobility

For head and neck cancer:

- Cervical and UE strength/mobility, grip strength, mouth opening
- Pain/tightness in neck/shoulder muscles

For gynecological and prostate cancers:

- Hip and lumbar ROM and strength

CANCER REHAB OCCUPATIONAL THERAPY EVALUATION

EVALUATION RECOMMENDATIONS:

Subjective:

- Type of cancer, including stage and grade
- Previous and/or pending surgeries
- Significant past medical history
- Lymph node dissection, including number of nodes removed and the number positive for cancer
- Chemotherapy treatment and side effects
- Radiation therapy and side effects including presence/absence of fibrosis, decreased joint ROM, tight tissues, and skin redness

- Pain, including rating scale type
- Presence/absence of numbness/tingling
- Lab Values including WBC, Platelets, Hemoglobin, and Absolute Neutrophil Count (ANC)
- FACIT-F: To assess cancer-related fatigue (see page 4 for additional details including administration)

Objective:

- Fine Motor testing
 - 9-hole peg test
 - Box and Block test
 - Grip testing
 - Pinch testing(lateral, 3 jaw, and pincer)
- UE sensation testing
 - Hot/Cold
 - Deep pressure

Specifics by cancer type:

For breast cancer:

- UE strength/ROM /grip strength

For head and neck cancer:

- Cervical and UE strength/mobility, grip strengthening/testing (Contraindicated for forearm free flap surgeries per surgeon recommendations-approx 8 weeks)
- Assess if splint use/hand therapy for forearm free flap
- Pain/tightness in neck/shoulder muscles

GOAL SETTING

- The following are examples that may be useful to incorporate into patient goal setting.
 1. Goals related to cancer-related fatigue:
 - Diminished concentration/attention
 - Decreased ability to participate in social activities
 - Decreased sleep or hypersomnia
 - Difficulty completing normal household activities
 - Fatigue lasting several hours after normal activities
- The following are proposed criteria from ICD 10 for cancer-related fatigue:
 1. Significant fatigue, diminished energy, or increased need to rest, disproportionate to any recent change in activity level, plus five or more of the following:
 - Complaints of generalized weakness, limb heaviness
 - Diminished concentration or attention
 - Decreased motivation or interest to engage in usual activities

- Insomnia or hypersomnia
 - Experience of sleep as unrefreshing or nonrestorative
 - Perceived need to struggle to overcome inactivity
 - Marked emotional reactivity (e.g., sadness, frustration, or irritability) to feeling fatigued
 - Difficulty completing daily tasks attributed to feeling fatigued
 - Perceived problems with short-term memory
 - Postexertional fatigue lasting several hours
2. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
 3. There is evidence from the history, physical examination, or laboratory findings that the symptoms are a consequence of cancer or cancer therapy.
 4. The symptoms are not primarily a consequence of comorbid psychiatric disorders such as major depression, somatization disorder, somatoform disorder, or delirium

FACIT-FATIGUE SCALE:

The functional outcome measure that has been chosen for the cancer rehabilitation program is the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F). The FACIT-F is a 13-item questionnaire that assesses self-reported fatigue and its impact upon daily activities and function. It was developed in 1994-1995 to meet a growing demand for the precise evaluation of fatigue associated with anemia in cancer patients. Subsequent to its development, it has been employed in over 70 published studies including over 20,000 people. See page 6 for a copy of the scale.

Note: the FACIT-F scale cannot be modified in any way from the original version.

Administration:

Patients will complete the FACIT-F upon initial evaluation and upon program discharge. The discipline that performs the first evaluation will have the patient complete the tool. Documentation of the score will be done in a Functional Questionnaires/Outcomes row in the OP PT Evaluation and the OP OT Evaluation. The FACIT-F score could also be entered on the daily documentation flowsheet in an Objective Measures row. The score will then flow to progress and discharge notes.

The discipline that discharges the patient from care last will again administer the same FACIT-F tool and document the score in the discharge note. The questionnaires will be discarded after the patient is discharged from therapy services (not scanned into Epic).

The FACIT scales are designed for patient self-administration, but can also be administered by interview format. For self-administration, patients should be instructed to read the brief directions at the top of the page. After the patient's correct understanding has been confirmed, he/she should be encouraged to complete every item in order without skipping any. Some patients may feel that a given question is not applicable to them and will therefore skip the item altogether. Patients should be encouraged to circle the response that is most applicable. If, for example, a patient is not currently receiving any

treatment, the patient should circle “not at all” to the question “I am bothered by side effects of treatment.” Average time to complete the questionnaire is 2-3 minutes.

REFERENCES:

- 1.) 1 RM information from YMCA Fitness Testing and Assessment Manual, 2000.
- 2.) Linda Boyle, PT. “Oncology Physical Therapy: Educational Strategies to Improve Safety and Outcomes” Presentation 2012.
- 3.) FACIT-F information from FACIT-F Scale Report 6/19/2012, Administration Guidelines Manual 082505, FACIT-Fatigue Scale Summary 6-27-07, and Scoring FACIT Fatigue Subscale v4-Revised accessed at FACIT.org-Member only Details page.

Appendix B

Fairview Cancer Rehabilitation

REDUCING SIDE EFFECTS, IMPROVING QUALITY OF LIFE

Cancer treatment and surgery can make you tired – both physically and mentally. Rehabilitation can help you stay independent and improve your quality of life.

Research shows that physical activity has many benefits for cancer survivors. It can reduce side effects of cancer treatment or surgery. It also can help you better tolerate treatment and continue with daily activities. Regular exercise reduces fatigue and improves mood. It also can improve sleep, decrease anxiety and strengthen your immune system.

Our program

Fairview's Cancer Rehabilitation Program helps you safely increase your activity level. Our physical and occupational therapists have additional training and experience working with cancer survivors. They will evaluate your needs and goals, and work with you and your physician to develop a personalized treatment plan.

Physical therapy can help you:

- increase strength and endurance
- improve range of motion, balance and flexibility
- decrease pain
- reduce nerve discomfort.

Occupational Therapy can help you:

- improve attention, organization and problem-solving
- learn ways to conserve your energy
- improve independence in daily activities
- recommend adaptive equipment.

For more information

The Cancer Rehabilitation Program requires a physician referral. Most health insurance, Medicare and Medicaid cover rehabilitation services.

For more information, call
612-273-6228.

Location

University of Minnesota Medical
Center, Fairview
Riverside West Building, Room F119 2312
S. 6th St.
Minneapolis, MN 55455
Scheduling: 612-273-6228

Related services

- Edema/ lymphedema (swelling) treatment
- Speech, language, swallowing therapy
- Transitional care unit
- Acute rehabilitation center
- Nutrition counseling
- Home care

For more information on these services, visit fairview.org or call 612-672-7272.

The program also provides education to help you prevent and reduce cancer-related physical and mental fatigue.

Appendix C

SF-12®

Answer every question by placing a check mark on the line in front of the appropriate answer. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

1. In general, would you say your health is:

- ☐ Excellent (1)
- ☐ Very Good (2)
- ☐ Good (3)
- ☐ Fair (4)
- ☐ Poor (5)

The following two questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:

- ☐ Yes, Limited A Lot (1)
- ☐ Yes, Limited A Little (2)
- ☐ No, Not Limited At All (3)

3. Climbing several flights of stairs:

- ☐ Yes, Limited A Lot (1)
- ☐ Yes, Limited A Little (2)
- ☐ No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:

- ☐ Yes (1)
- ☐ No (2)

5. Were limited in the KIND of work or other activities:

- ☐ Yes (1)
- ☐ No (2)

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like:

- ☐ Yes (1)
- ☐ No (2)

7. Didn't do work or other activities as CAREFULLY as usual:

- ☐ Yes (1)
- ☐ No (2)

8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?

- ☐ Not At All (1)
- ☐ A Little Bit (2)
- ☐ Moderately (3)
- ☐ Quite A Bit (4)
- ☐ Extremely (5)

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?

- ☐ All of the Time (1)
- ☐ Most of the Time (2)
- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

10. Did you have a lot of energy?

- ☐ All of the Time (1)
- ☐ Most of the Time (2)
- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

11. Have you felt downhearted and blue?

- ☐ All of the Time (1)
- ☐ Most of the Time (2)
- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?

- ☐ All of the Time (1)
- ☐ Most of the Time (2)
- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

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Appendix D

FACIT-Fatigue Scale (Version 4)

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.**

		Not at all	A little bit	Some- what	Quite a bit	Very much
HI7	I feel fatigued	0	1	2	3	4
HI 12	I feel weak all over.....	0	1	2	3	4
An1	I feel listless (“washed out”)	0	1	2	3	4
An2	I feel tired.....	0	1	2	3	4
An3	I have trouble <u>starting</u> things because I am tired	0	1	2	3	4
An4	I have trouble <u>finishing</u> things because I am tired	0	1	2	3	4
An5	I have energy.....	0	1	2	3	4
An7	I am able to do my usual activities.....	0	1	2	3	4
An8	I need to sleep during the day	0	1	2	3	4
An 12	I am too tired to eat	0	1	2	3	4
An 14	I need help doing my usual activities.....	0	1	2	3	4
An 15	I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
An 16	I have to limit my social activity because I am tired	0	1	2	3	4

Appendix E

FACIT-Fatigue Subscale Scoring Guidelines (Version 4)

Scoring:

All FACIT scales are scored so that a high score is good. As each of the 13 items of the FACIT-F Scale ranges from 0-4, the range of possible scores is 0-52, with 0 being the worst possible score and 52 the best. To obtain the 0-52 score each negatively-worded item response is recoded so that 0 is a bad response and 4 is good response. All responses are added with equal weight to obtain the total score. In cases where some answers may be missing, a total score is prorated from the score of the answered items, so long as more than 50% of the items (i.e., at least 7 of 13) were answered.

FACIT-Fatigue Subscale Scoring Guidelines (Version 4)

- Instructions:*
1. Record answers in "item response" column. If missing, mark with an X
 2. Perform reversals as indicated, and sum individual items to obtain a score.
 3. Multiply the sum of the item scores by the number of items in the subscale, then divide by the number of items answered. This produces the subscale score.
 4. **The higher the score, the better the QOL.**

<u>Subscale</u>	<u>Item Code</u>	<u>Reverse item?</u>		<u>Item response</u>	<u>Item Score</u>
FATIGUE SUBSCALE	HI7	4	-	_____	= _____
	HI12	4	-	_____	= _____
	An1	4	-	_____	= _____
	An2	4	-	_____	= _____
	An3	4	-	_____	= _____
	An4	4	-	_____	= _____
	An5	0	+	_____	= _____
	An7	0	+	_____	= _____
	An8	4	-	_____	= _____
	An12	4	-	_____	= _____
	An14	4	-	_____	= _____
	An15	4	-	_____	= _____
	An16	4	-	_____	= _____

Sum individual item scores: _____

Multiply by 13: _____

Divide by number of items answered: _____

_____ = Fatigue Subscale score

Score range: 0-52

Interpretation of Scores:

The average score in the US general population is 40, with standard deviation (SD) of approximately 10. Thus, any effort to elevate or maintain a FACIT-F score above 30 would help keep the person within normal limits, as defined by plus or minus one SD. If a person were to have a 3-4 point increase or decrease in score, one can reasonably classify that person as having changed. Thus the minimally important difference (MID) appears to be in the range of 3-4 points.

Appendix F

Follow up Questionnaire

1. Has your health status changed in the last 4 months? (i.e. relapse of cancer, new diagnosis)

- ☐ Yes
- ☐ No

Comment (optional) :

2. Are you participating in a community wellness program? (examples: YMCA, Lifetime Fitness, group classes, etc)

- ☐ Yes
- ☐ No

Comment (optional) :

3. About how many minutes a week are you exercising? (Including Home Exercise Program and group fitness classes)

- ☐ 0 minutes
- ☐ 30 minutes or less
- ☐ 31 to 60 minutes
- ☐ 61 to 90 minutes
- ☐ 91 to 120 minutes
- ☐ 121 to 150 minutes
- ☐ 151 minutes or more

4. If you are experiencing pain, please indicate the intensity of your pain over the last 24 hours on a scale of 0 to 10. 0 indicates no pain and 10 indicates your worst imaginable pain. (Circle your pain rating)

No pain					Worst imaginable pain					
0	1	2	3	4	5	6	7	8	9	10

Appendix G

Follow up Survey Cover Letter

Dear Participant,

While attending Cancer Rehabilitation at Fairview, you consented to being a part of a study that analyzes the change in your quality of life, fatigue levels, and physical well being before and after physical therapy. Enclosed you will find:

1. Follow up Questionnaire
2. SF-12
3. FACIT-Fatigue Scale

Upon your earliest convenience, please fill out these three forms and send them back in the addressed and stamped envelope.

Thank you so much for your participation in this study.

Sincerely,
St. Catherine University Student Research Team

Appendix H
Sample Data Collection Sheet

Demographics

Age	
Medical Diagnosis	
Time Since Treatment for Cancer	
# of Physical Therapy Visits	
# of Occupational Therapy Visits	
Presence of Anemia (Y/N)	

Outcome Measures

	PRE	POST	2-month follow up
FACIT-F			
SF-12			
6MWT			
TUG			
GRIP STRENGTH			
PAIN			
HEALTH STATUS CHANGED? YES			
PARTICIPATING IN WELLNESS PROGRAM? YES			
MINUTES OF EXERCISE			

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